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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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JEANETTE GELBER & HUGH GELBER,

Plaintiffs,

-against-

MEMORANDUM
AND
ORDER

STRYKER CORPORATION, HOWMEDICA OSTEONICS, & STRYKER ORTHPEDICS, INC.,

09 Civ. 1322

Defendants.
----------x

P. KEVIN CASTEL, United States District Judge:

In this action, plaintiff Jeanette Gelber asserts multiple medical device liability claims against Stryker Corporation, Howmedica Osteonics, and Stryker Orthopedics, Inc.,[1] (collectively "Stryker") seeking to recover damages arising from the surgical implantation of an artificial hip prosthesis known as the Trident™ hip replacement system ("Trident System"). She alleges that because the Trident System was defective, she experienced pain and eventually required an additional surgical procedure to have a new hip prosthesis implanted. State law claims of negligence, breach of express and implied warranty, and strict products liability are asserted. Plaintiff Hugh Gelber seeks to recover for various derivative injuries he suffered as a result of the injury to his wife. Defendants move to dismiss the Amended Complaint on the grounds that plaintiffs' claims are preempted by federal law and fail to state a claim for relief pursuant to Rule 12(b)(6), Fed. R. Civ. P. For the reasons stated below, defendants' motion to dismiss is granted in part and denied in part.

[1] Defendants note that no corporate entity by the name "Stryker Orthopedics, Inc." exists. Howmedica Osteonics Corp. does business under the name "Stryker Orthopaedics."

BACKGROUND

I. Factual History

Mrs. Gelber underwent a total right hip arthroplasty on July 21, 2004 at Lenox Hill Hospital in New York, New York. (Am. Compl. ¶ 7.) The Trident System was the prosthetic device implanted into Mrs. Gelber during the surgical procedure. (Am. Compl. ¶ 19.) Plaintiffs allege that the Trident System components implanted during this procedure were manufactured either in defendants' Mahwah, New Jersey plant or its Cork, Ireland plant. (Am. Compl. ¶ 21.) In Spring 2007, Mrs. Gelber began to experience pain in her right hip and heard squeaking and/or creaking emanating from her right hip. (Am. Compl. ¶ 22.) Mrs. Gelber later experienced numbness and burning in her calf and loss of balance. (Am. Compl. ¶ 24.) Despite undergoing conservative treatment, Mrs. Gelber required hip revision surgery on January 26, 2009 to remove the Trident System and implant a different prosthetic device. (Am. Compl. ¶ 26.) Upon removal and inspection of the Trident System, Mrs. Gelber's surgeon noted a stripe on the ceramic head component, as well as wear on the ceramic insert. (Am. Compl. ¶ 27.)

The FDA approved the Trident System for sale in the United States on February 3, 2003. (Am Compl. ¶ 14.) The parties agree that the Trident System implanted into Mrs. Gelber was a Class III medical device; the significance of this classification is explained below. (Pls. Mem. 6; Defs. Mem. 12.) However, plaintiffs also allege that "[a]fter the conditional approval, but before implantation into [p]laintiff . . . , [d]efendants modified the Trident System through submissions pursuant to the abbreviated review process under to [sic] 21 U.S.C. 510(k) on several occasions, including but not limited to May 25, 2004, by increasing wall thickness in the Trident "T" Acetabular Shells." (Am. Compl. ¶ 65.) Plaintiffs further allege that this specific modification, approved under the abbreviated 510(k) review process, "was made in part

to address the very defects in the Stryker Trident System that caused [p]laintiff's implant to fail." (Am. Compl. ¶ 66.)

II. Procedural History

On January 22, 2009, plaintiffs commenced this action by filing the Summons and Verified Complaint with the Clerk of the Supreme Court of the State of New York, County of Rockland. (Docket #1.) Defendants removed the case to this Court on February 13, 2009, alleging diversity of citizenship and an amount in controversy in excess of the jurisdictional threshold. 28 U.S.C. § 1332. Defendants then filed a motion to dismiss the Complaint on March 13, 2009. (Docket #7.)

Chief Judge Loretta A. Preska, in a September 14, 2010 Order and Opinion, granted defendants' motion to dismiss, pursuant to Rule 12(b)(6), Fed. R. Civ. P. Gelber v. Stryker Corp., __ F. Supp. 2d __, 2010 WL 4740432, at *1 (S.D.N.Y. Sep. 14, 2010). The Court concluded that plaintiffs' claims of negligence, strict liability, and breach of warranty were preempted under the under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act ("MDA"). Id. at *6 ("The failure to allege state law claims that are parallel to federal requirements is the primary ground on which the Court grants Defendants' motion to dismiss.") The Court also concluded that plaintiffs failed to plead properly the elements of their manufacturing defect claim and their breach of express warranty claim. Id.

In granting defendants' motion to dismiss, Chief Judge Preska concluded that plaintiffs "failed to allege that their claims are parallel to federal regulations so as to avoid preemption and failed to properly plead the elements of their claim." Id. at *7. Plaintiffs initially asserted "claims based upon failure to warn, improper labeling, improper or misleading marketing and/or defective design," but these claims were withdrawn. Id. at *4. The Court

granted permission to amend the Complaint and the plaintiffs filed the Amended Complaint on September 30, 2010. (Docket #18.) The Amended Complaint is starkly different from the initial Complaint; the Amended Complaint alleges that defendants violated multiple federal regulations, whereas the initial Complaint makes no similar allegations.

The Amended Complaint alleges five counts including: (1) strict products liability based on a defective manufacturing claim; (2) negligence; (3) breach of implied warranty of merchantability; (4) breach of express warranty; and (5) loss of consortium. These counts are alleged under individual headings setting forth the specific claim. Under a heading entitled "Facts," plaintiffs also set forth multiple allegations that can be construed as alleging a cause of action for failure to warn, based on the defendants' alleged failure to take action to update the warning information on the Trident System's label, (Am. Compl. ¶¶ 29-37), and a cause of action for failure to report, based on defendants' alleged failure report to the FDA the true and accurate incidence of a squeaking noise emanating from the Trident System. (Am. Compl. ¶ 37.)

On October 27, 2010, defendants filed a motion to dismiss the Amended Complaint pursuant to Rule 12(b)(6), Fed. R. Civ. P. (Docket #21.) The case was reassigned to the undersigned on November 15, 2010. (Docket #24.) Defendants move to dismiss the Amended Complaint asserting the same grounds for dismissal as their first motion; specifically that plaintiffs' claims are preempted by federal law and, to the extent they are not preempted, they fail to state a claim for relief pursuant to Rule 12(b)(6), Fed. R. Civ. P. (Defs. Mem. 5.)

THE MEDICAL DEVICE AMENDMENTS

"The Federal, Food, Drug, and Cosmetic Act (FDCA) . . . , as amended, 21 U.S.C. § 301 et seq., has long required FDA approval for the introduction of new drugs into the market. Until [Congress enacted the MDA], however, the introduction of new medical devices

was left largely for the States to supervise as they saw fit." Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008). The development of new medical technology and equipment, such as artificial heart valves and heart pacemakers, and the increasingly severe injuries individuals sustained from use of these devices prompted concern over the safety of medical devices. Medtronic, Inc. v. Lohr, 518 U.S. 470, 476 (1996). The Dalkon Shield, an intrauterine contraceptive device, was one specific medical device introduced in the 1970s that raised public concern because its use "resulted in a disturbingly high percentage of inadvertent pregnancies, serious infections, and even, in a few cases, death." Lohr, 518 U.S. at 476. Concern over these increasingly complex and invasive medical devices prompted some states, such as California, to enact law requiring premarket approval of medical devices. Riegel, 552 U.S. at 315. In 1976, Congress enacted the MDA, "which swept back some state obligations and imposed a regime of detailed federal oversight." Id. at 316.

The MDA classifies medical devices into three categories based on the risk they pose to the public and provides greater oversight for devices in the highest risk classification level, Class III. Id. at 316-17. A medical device is "Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.' " Id. at 317 (citing 21 U.S.C. § 360c(a)(1)(C)(ii)).

New Class III devices undergo a rigorous premarket approval process unless they are found to be "substantially equivalent" to another device that is exempt from premarket approval. Id. (citing 21 U.S.C. §§ 360c(f)(1)(A)). The approval process for devices that are

"substantially equivalent," referred to as the section 510(k) approval process, is much less demanding than the premarket approval process and is the process the majority of devices undergo in order to receive FDA approval. See id. (explaining that "[i]n 2005 . . . the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.") The Supreme Court has described the premarket approval process as follows:

> Premarket approval is a rigorous process. A manufacturer must submit what is typically a multivolume application. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling. Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, and may request additional data from the manufacturer.
>
> The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds there is a reasonable assurance of the device's safety and effectiveness. The agency must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives. It approved, for example, under its Humanitarian Device Exemption procedures, a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent.

Id. at 317-318 (internal citations, alterations and quotations omitted). Review of the device's proposed labeling is included in the premarket approval process. 21 U.S.C. § 360e(d)(1)(A).

Even after a device becomes receives premarket approval, the device remains subject to FDA regulations. The manufacturer may not change its design, manufacturing process, labeling or other attributes that would affect safety or effectiveness without filing a supplemental premarket approval application. 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a). These supplemental applications are "evaluated under largely the same

criteria as an initial application." Riegel, 552 U.S. at 319; 21 U.S.C. § 360e(d)(6)(A)(i); 21 CFR § 814.39(c). Although "the burden for determining whether a [supplemental application] is required is primarily on the [premarket approval] holder," the regulations specifically require a manufacturer to submit a supplemental premarket approval application for label changes that affect the safety or effectiveness of the device. 21 C.F.R. §§ 814.39(a); 814.39(a)(2). While the supplemental premarket approval application is pending, a manufacturer may augment the warnings on the device's label. 21 C.F.R. § 814.39(d) (providing that a manufacturer may temporarily change a label to enhance safety pending FDA approval of the change); Brooks v. Howmedica, Inc., 273 F.3d 785, 796 (8th Cir. 2001), cert denied, 535 U.S. 1956 (2002) (explaining that these temporary label "changes are valid only after the manufacturer has submitted a [s]upplemental [premarket approval application] and only during the pendency of that application.")

Post-approval reporting requirements are also imposed on medical device manufacturers. 21 U.S.C. § 360i. These include obligations to submit reports from unpublished or published clinical investigations or studies involving the device, which the manufacturer knows or reasonably should know. 21 C.F.R. § 814.84(b)(2). Manufacturers must also report incidents in which the device "[m]ay have caused or contributed to a death or serious injury" or "[h]as malfunctioned and this device or a similar device [marketed by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a). "The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." Riegel, 552 U.S. at 319-20 (citing 21 U.S.C. §§ 360e(e)(1); 360h(e)). The FDA also has the authority to order a labeling change based

on newly acquired information. 21 U.S.C. § 360f(a)(2). If the FDA concludes that a device "presents an unreasonable risk of substantial harm to the public," it may require the manufacturer to notify all affected individuals, or require repair or replacement of the device. 21 U.S.C. § 360h.

Medical devices in general, not just Class III devices, are subject to the FDA's current good manufacturing practice requirements (CGMP requirements). 21 U.S.C. § 360j(f); 21 C.F.R. §§ 820 et seq. These requirements set forth a quality control system and "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R § 820.1(a)(1). They are in place "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." 21 C.F.R. § 820.1(a)(1). To comply with the CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements . . . leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective." Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 279 (E.D.N.Y. 2009).

STANDARD GOVERNING MOTION TO DISMISS

Rule 8(a)(2), Fed. R. Civ. P., requires "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955, 1964 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)) (ellipsis

in original). To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must provide the grounds upon which the claims rest, through factual allegations sufficient to raise a right to relief above the speculative level. ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007) (quoting Twombly, 127 S. Ct. at 1965). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Achcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009). "The plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully." Id. Legal conclusions and "[t]hreadbare recitals of the elements of a cause of action" do not suffice to state a claim, as "Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." Id. at 1949-50. The Supreme Court has described the motion to dismiss standard as encompassing a "two-pronged approach" that requires a court first to construe a complaint's allegations as true, while not bound to accept the veracity of a legal conclusion couched as a factual allegation. Id. Second, a court must then consider whether the complaint "states a plausible claim for relief," which is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. Although the Court is limited to facts as stated in the complaint, it may consider exhibits or documents incorporated by reference without converting the motion into one for summary judgment. See Int'l Audiotext Network, Inc. v. AT&T, 62 F.3d 69, 72 (2d Cir. 1995). A statute of limitations defense, based exclusively on dates contained within the complaint or appended materials, may be properly asserted by a defendant in a Rule 12(b)(6) motion. Ghartey v. St. John's Queens Hosp., 869 F.2d 160, 162 (2d Cir. 1989).

PREEMPTION UNDER THE MEDICAL DEVICE AMENDMENTS

The MDA includes an explicit preemption clause, which states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).[2]

In Riegel, the Supreme Court held that for section 360k(a) preemption purposes, (1) the FDA's rigorous premarket approval process imposes federal "requirements" that triggered the preemption clause and (2) that common law product liability claims result in "state requirements" that are preempted to the extent they relate to the safety and effectiveness of the device and are "different from, or in addition to," the federal requirements established by premarket approval. Riegel, 552 U.S. at 322-25, 330 (quoting 21 U.S.C. § 360k(a)). The Court noted that "section 360k(a) does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id. at 330. However, "[t]he contours of the parallel claim exception were not addressed in Riegel and are as-yet ill-defined." In re Medtronic, Inc. Sprint Fidelis Leads, 623 F.3d 1200, 1204 (8th Cir. 2010). The claims at issue in Riegel all involved alleged violations of "state tort law notwithstanding compliance with the relevant federal requirements . . . ." Riegel, 552 U.S. at 330.

[2] This is no allegation that any relevant subsection (b) exception applies in this action.

The Supreme Court, in Buckman, addressed the issue of implied preemption under the MDA. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). Noncompliance with a MDA provision does not in and of itself provide a cause of action for a private litigant. Id. at 349 n.4. All actions to enforce the FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a).

In reconciling the scope of section 360k(a) in light of these two cases, the Eight Circuit explained,

> Riegel and Buckman create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the [Food, Drug, and Cosmetic Act] (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

Medtronic Leads, 623 F.3d at 1204 (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D.Minn. 2009)). "The Supreme Court thus has made clear that section 360(k) protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law." Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010).

The Supreme Court has described a three-step analysis a court must undertake to determine whether a state common-law claim is preempted by section 360k(a). Riegel, 552 U.S. at 321-22; Wolicki-Gables v. Arrow Intern., Inc., 2011 WL 780684, at *4 (11th Cir. 2011); Horowitz, 613 F. Supp. 2d at 279; Covert v. Stryker Corp., 2009 WL 2424559, at *3 (M.D.N.C. 2009). First, a court must find that federal requirements are imposed on the particular medical device. Riegel, 552 U.S. at 321-22. If federal requirements are imposed, then the court must determine whether a plaintiff's claims are based on a state requirement that "relates to the safety

or effectiveness of the device or to any other matter included in a requirement applicable to the device." Id. at 323. Third, the claim will be preempted where the court "determine[s] [that] the [plaintiff's] common-law claims are based upon New York requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." Id. at 321-22 (quoting 21 U.S.C. § 360k(a)).

As to step one of the analysis, the parties agree that the Trident System was a Class III medical device that underwent the premarket approval process. Undergoing this process imposed extensive device-specific federal requirements on the device sufficient to satisfy the first prong of the analysis. See id. at 322-23 (stating that the premarket approval process imposes requirements under the MDA which are specific to individual devices.) With respect to step two, plaintiffs do not dispute that the state-law requirements on which their claims are based relate to the safety or effectiveness of the device. Here, as in Riegel, "[s]afety and effectiveness are the very subjects of [plaintiffs'] common-law claims . . . ." Id. at 323. Thus, this Court will focus its preemption analysis on whether plaintiffs' New York common-law claims would impose requirements that are " 'different from, or in addition to' the federal ones, and relate to safety and effectiveness."[3] Id. at 321-22 (quoting 21 U.S.C. § 360k(a)).

[3] In Riegel, the Supreme Court addressed the preemptive impact of 21 C.F.R. § 808.1(d)(1), "an FDA regulation which states that the MDA's pre-emption clause does not extend to certain duties, including '[s]tate or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.' " Riegel, 552 U.S. at 328 (citing 21 C.F.R. § 808.1(d)(1)). After stating that section "808.1(d)(1) can add nothing to our analysis but confusion," the Court noted that "the regulation fails to alter our interpretation of [section 360k(a)] insofar as the outcome of this case is concerned." Id. at 328-29. Similarly, this Court does not view this provision as one that alters the preemption analysis set forth in this opinion, such that it would alter whether any of plaintiffs' claims are preempted.

The parallel claim principle was further described by the Seventh Circuit as follows:

> In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "*genuinely* equivalent." State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.

McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005), cert denied, 547 U.S. 1003 (citing Bates v. Dow Agrosciences LLC, 544 U.S. 431, 454 (2005)). "Plaintiffs cannot simply incant the magic words '[defendants] violated FDA regulations' in order to avoid preemption." In re Medtronic, 592 F. Supp. 2d 1147, 1158 (D.Minn. 2009), aff'd, 623 F.3d 1200 (8th Cir. 2010) (citing Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1301 (D.Colo. 2008)). " 'To properly allege parallel claims, the complaint must set forth facts' pointing to specific PMA requirements that have been violated.' " Wolicki-Gables, 2011 WL 780684, at *5 (quoting Parker, 584 F. Supp. 2d at 1301). Plaintiffs must also allege how the alleged violation is linked to the plaintiffs' injury. Id. at *5 (citing Ilarraza v Medtronic. Inc., 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).

APPLICATION

A. Plaintiffs Manufacturing Defect Claims Are Not Preempted and State A Claim for Relief

The Amended Complaint alleges, under New York state common law negligence and strict products liability theories, that defendants defectively manufactured the Trident System components Mrs. Gelber received by failing to adhere to the FDA premarket approval specifications and other FDA regulations regarding the device's manufacturing. (Am. Compl. ¶ 84.) Under New York law, in order "[t]o plead and prove a manufacturing flaw under either

negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (quoting Caprara v. Chrysler Corp., 52 N.Y.2d 114, 128-29 (1981)).

Construing plaintiffs' allegations liberally, plaintiffs allege that the Trident System Mrs. Gelber received was defective because it was manufactured with "manufacturing residuals" that exceeded Styker's internal acceptance criteria. (Am. Compl. ¶¶ 46, 48, 52, 57, 81.) Plaintiffs allege that this made the device "adulterated," as defined under 21 U.S.C. § 351(h), and "unreasonably dangerous and unfit for [its] intended purpose." (Am. Compl. ¶ 76.) Section 351(h) defines an adulterated device, in part, as a device where "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable" CGMP requirements. 21 U.S.C. § 351(h). A CGMP requirement relating to manufacturing material, set forth in section 820.70, provides:

> "Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented."

21 C.F.R. § 820.70(h).

Defendants argue that plaintiffs' manufacturing claims are preempted under section 360k(a) because the claims seek to impose different or additional requirements on the device. (Defs. Mem. 6-7.) However, defendants have failed to explain how, under these facts, alleging that the device was defective because it was not manufactured in accordance with the

CGMP requirements set forth in the Act, imposes a different or additional requirement on the device within the meaning of section 360k(a). In addition, the FDA regulations themselves reveal the FDA's understanding of section 360k(a) with respect to a claim alleging that a manufacturer produced an adulterated device. See 21 C.F.R. § 808.1(d). The regulations state, "[g]enerally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition [may] be preempted . . . ." 21 C.F.R. § 808.1(d)(6)(ii). Based on the claim as pled by plaintiffs, this Court sees no additional substantive requirement that would be imposed on defendants. Rather, imposing liability would serve to reinforce Styker's obligation to comply with federal regulations. See Riegel v. Medtronic, Inc., 451 F.3d 104, 124 (2d Cir. 2006), aff'd, 552 U.S. 312 (2008) (quoting Lohr, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part) ("To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply" with federal regulations.)

Defendants also argue that plaintiffs do not point to "evidence of device-specific violations of federal law" and fail to link the federal violation to Mrs. Gelber's injury. (Defs. Mem. 6-7, 9-10.) Plaintiffs do not expressly state which specific provision set forth in the CGMP requirements the defendants violated in manufacturing the allegedly "adulterated" Trident System implanted in Mrs. Gelber. However, plaintiffs describe (1) a November 28, 2007 warning letter (the "Warning Letter") sent from the FDA to Stryker regarding the Stryker manufacturing plant in Mahwah, New Jersey and (2) a January 22, 2008 voluntary recall of Trident PSL and Hemispherical Cups manufactured in the Cork, Ireland Facility (the "Recall"). (Am. Compl. ¶¶ 38-53.) The substance of these allegations indicate that plaintiffs seek to prove

that Mrs. Gelber's Trident System was adulterated because some of the components, as a result of the manufacturing process, contained excess levels of manufacturing residue. By pleading the conduct which plaintiffs allege violated the CGMP requirements, describing evidence of the alleged violation, and directing plaintiffs to the CGMP requirements generally, plaintiffs have given defendants more than ample notice of the alleged violation of federal law. See Bausch, 630 F.3d at 560 (concluding that the plaintiff's defective manufacturing claims relating to a class III medical device that underwent the premarket approval process were not preempted and met the Twombly pleading standard despite the plaintiff's failure to "specify the precise defect or the specific federal regulatory requirements that were allegedly violated.") But see Parker, 584 F. Supp. 2d at 1301 (dismissing claims alleging a manufacturing defect for lack of factual detail where the complaint referenced two FDA-issued warning letters and generally alleged that the Trident System was defective because "the manufacturing processes for the device and certain of their [sic] components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices" and that the device was sold "in direct violation of the Code of Federal Regulations" which proximately caused plaintiff's injuries.)

Plaintiffs also have plausibly alleged that the manufacturing defect, producing a device with excessive manufacturing residue, caused Mrs. Gelber's injury. There is no heightened pleading requirement applicable to these claims, so the Twombly standard outlined above applies. See Bausch, 630 F.3d at 560.

In attempting to link the federal violation to the injuries Mrs. Gelber sustained, plaintiffs describe Stryker's Recall and the Warning Letter as support for the allegation that Mrs. Gelber was injured because her implant was manufactured with excessive manufacturing residue. Defendants described the reason for the recall as follows:

> "During a recent cleaning process evaluation at the Cork, Ireland facility, some of the parts that were tested exceeded Stryker Orthopedics' internal acceptance criteria for manufacturing residual levels. Based on these data, some of the Trident Hemispherical and PSL Acetabular Shells manufactured since 1998 at the Cork, Ireland facility may have exceeded this internal acceptance criteria."

(Am. Compl. ¶ 48.) Plaintiffs allege that "[a] company's voluntary recall of a medical device and the FDA's classification of that action as a recall establishes that the device violates FDA regulations . . . ." (Am. Compl. ¶ 51.) Plaintiffs also describe the FDA Warning Letter defendants received regarding the Mahwah, New Jersey plant, in which the FDA allegedly identified the root causes of squeaking "as breaks in the lubrication layer between the bearing surfaces that could be caused by several different factors and could ultimately lead to the formation of a wear scar, or a stripe which is a located abraded area on the implant surface." (Am. Compl. ¶ 42.)

It is certainly plausible that by violating internal acceptance criteria, this conduct also violated manufacturing specifications set forth in the premarket approval application. Courts have acknowledged the difficulty in alleging "the precise defect or the specific federal regulatory requirements that were allegedly violated" for Class III medical devices that undergo the PMA process because certain premarket approval documents are confidential and the public does not have access to the complete versions of these documents. Bausch, 630 F.3d at 560; Medtronic Leads, 623 F.3d at 1206 (acknowledging the importance of discovery for plaintiffs who seek to plead a parallel claim and lack access to the specific federal requirements in the premarket approval application); 21 C.F.R. § 814.9(h)(1) (providing that "[m]anufacturing methods or processes, including quality control procedures" are generally are not available for public disclosure). The Seventh Circuit has noted that "much of the critical information [a plaintiffs would need to plead a parallel claim with specificity] is kept confidential as a matter of

federal law." Bausch, 630 F.3d at 560; Medtronic Leads, 623 F.3d at 1211, n.7 (Melloy, J., dissenting in part).

Construing the allegations liberally, plaintiffs have plausibly alleged that the excessive levels of manufacturing residue was one of the "several different factors" that ultimately led to breaks in the lubrication layer and the stripe found on Mrs. Gelber's implanted Trident System. Plaintiffs also have plausibly alleged a federal violation and linked this violation to Mrs. Gelber's injury sufficient to withstand a motion to dismiss and permit discovery to proceed. See Phillips v. Stryker Corp., 2010 WL 2270683, at *7 (E.D.Tenn. June 3, 2010) (quoting the amended complaint) (concluding that plaintiff "link[ed] his state law claims to [federal] violations . . . by alleging, for example, that the 'Trident acetabular cup contained a manufacturing defect in that it was adulterated as a result of being manufactured in violation of FDA regulations and requirements . . . such that manufacturing residuals remained on the prosthesis after its manufacture' which 'proximately caused plaintiff's acetabular cup to become loose necessitating revision surgery.' ")

In arguing that plaintiffs failed to allege a parallel claim to survive preemption, defendants also assert that plaintiffs must point to a "federal violation that affected the specific implanted device." (Defs. Mem. 10-11.) Courts have disagreed as to whether a plaintiff can plead a parallel claim by alleging that a defendant violated a CGMP requirement. Compare Bausch, 630 F.3d at 554 (analyzing the cases with diverging views on this issue and concluding that "we do not see a sound legal basis for defendants' proposal to distinguish between general requirements and 'concrete, device-specific' requirements") with Ilarraza, 677 F. Supp. 2d at 588 (explaining that, where plaintiff relied upon only CGMPs requirements to state a parallel claim, the claims were preempted "because no regulation relied upon refers specifically to the medical

device at issue"); In re Medtronic, 592 F. Supp. 2d at 1157 (stating that the CGMPs are "simply too generic, standing alone, to serve as the basis for [p]laintiffs' manufacturing-defect claims.") Some courts finding that claims alleging a CGMP violation are preempted have concluded that the CGMPs are not specific enough to permit a jury to determine whether the defendants did in fact violate them. See Bausch, 630 F.3d at 554 (collecting cases where federal courts have found that these regulations are too generic and vague to serve as the basis for a parallel claim). Other courts have found that the CGMPs are open to a particular manufacturer's interpretation, and "allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits." Ilarraza, 677 F. Supp. 2d at 588.

The regulations state that the CGMP requirements "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of *all finished devices* intended for human use." 21 C.F.R. § 820.1(a)(1) (emphasis added). Thus, devices approved under the premarket approval process must comply with CGMP requirements. Moreover, the FDA's Warning Letter described by plaintiffs indicates that the CGMP requirements were incorporated into the Trident System's premarket approval application. (Am. Compl. ¶ 39.) The Warning Letter concluded that the premarket approved Class III device described in the letter was adulterated because it failed to comply with the CGMP requirements. (Am. Compl. ¶ 39.)

District courts have noted that the CGMP requirements "are intended to serve only as 'an umbrella quality system' providing 'general objectives' medical device manufacturers must seek to achieve." Ilarraza, 677 F. Supp. 2d at 588 (citing Horowitz, 613 F. Supp. 2d at 278). This, however, does not necessarily mean that claims premised on such a violation cannot serve as a basis for pleading a parallel claim. The federal regulations provide:

> "State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements."

21 C.F.R. § 808.1(d). Construing this language in light of Riegel, this Court concludes that a defective manufacturing claim based upon a violation of the referenced CGMP requirement is not preempted. See Riegel, 552 U.S. at 322-23 (stating that the premarket approval process imposes requirements under the MDA which are specific to individual devices.)

The Sixth and Seventh Circuits have also concluded that CGMP requirements may serve as grounds for pleading a parallel claim. See Bausch, 630 F.3d at 555 (reviewing the Sixth and Eighth Circuit decisions and agreeing with the Sixth Circuit that there is no "sound legal basis for defendants' proposal to distinguish between general requirements and 'concrete, device-specific' requirements"); Howard v. Sulzer Orthopedics, Inc., 382 Fed.Appx. 436, 440 (6th Cir. 2010) (finding, in an unpublished opinion, that where a plaintiff identified a specific CGMP believed to be violated, it was "not so vague as to be incapable of enforcement.") In explaining its position, the Seventh Circuit explained that to distinguish between device-specific requirements and the more general CGMP requirements in determining whether plaintiffs sufficiently plead parallel claims would "leave injured patients without any remedy for a wide range of harmful violations of federal law." Bausch, 630 F.3d at 555. In demonstrating this point, the court sets forth a hypothetical situation where a patient developed an infection after the patient received an implanted hip replacement system contaminated with worker's blood or mucus in violation of a CGMP requirement mandating each manufacturer to "establish and maintain procedures to prevent contamination of equipment or product by substances that could

reasonably be expected to have an adverse effect on product quality." Bausch, at 555 (quoting 21 C.F.R. § 820.70(e)). If a court were to require the plaintiff to allege a "concrete" and "product-specific" violation, the plaintiff in this hypothetical would not be able to plead a parallel claim and would therefore be without a remedy.

Although some CGMP requirements only require a manufacturer "to establish and maintain procedures," such as 21 C.F.R. § 820.100, discussed below, 21 C.F.R. § 820.70(h), the CGMP requirement addressing excessive manufacturing material, also requires the manufacturer "to ensure that it is removed or limited to an amount that does not adversely affect the device's quality." 21 C.F.R. § 820.70(h). This Court construes this language to require a manufacturer to actually remove or reduce the excess material to a level that does not adversely affect the functioning of the device. See Howard, 382 Fed.Appx. at 441 (interpreting 21 C.F.R. § 820.70(h) to mean that actual removal of the material is required.)

This Court concludes that plaintiffs' claim alleging that defendants produced a defective product because it was manufactured with excess manufacturing residue would not impose any additional burdens on the defendants not otherwise imposed by federal law. Plaintiffs have therefore stated a claim upon which relief can be granted.

B. Plaintiffs' Failure to Warn and Failure to Report Claims Are Dismissed

Plaintiffs allege that defendants failed to update information on the Trident System label to reflect accurately the incidence of squeaking and the associated adverse effect of grinding associated with the squeaking. (Am. Compl. ¶ 29.) Plaintiffs also allege that defendants failed to report to the FDA clinical investigations indicating a squeaking rate higher than reported on the device's label and an associated grinding. (Am. Compl. ¶ 37.) By failing to update the label information, plaintiffs allege that defendants failed to provide Mrs. Gelber with

sufficient information to decide whether to have a Trident System surgically implanted. (Am. Compl. ¶ 29.) Plaintiffs specifically allege that had Mrs. Gelber known the incidence of squeaking was higher than reported on the label, she would not have had a Trident System implanted. (Am. Compl. ¶ 64.)

Plaintiffs' failure to warn and failure to report claims stem from allegations that the Trident System label inaccurately stated the incidence of squeaking associated with the Trident System. (Am. Compl. ¶ 29.) The label stated that "[a]n audible noise during motion, such as a squeak, has been reported for patients receiving a ceramic-on-ceramic bearing couple." (Am. Compl. ¶ 29.) The label further provided that "[a] 0.5% rate of squeaking noise has been reported in the clinical study with the Trident Alumina Insert." (Am. Compl. ¶ 29.) In an effort to establish the factual basis for these claims, plaintiffs reference findings by several "orthopedic physicians" presented at a November 2006 American Association of Hip and Knee Surgeons fall meeting. (Am. Compl. ¶ 32.) One physician at the meeting "reported that, between 2002 and 2005, physicians at the Rothman Institute reported the prevalence rate of audible sound (squeaking) associated with the Stryker Trident System as 2.7% (30 of 1,056 total with 1 of 99 in the first year; 13 of 388 in year two and 16 of 567 in year three.)" (Am. Compl. ¶ 33)(emphasis removed.) This plausibly indicates that the incident rate, as indicated by this study, was approximately 1.0% between 2002 and 2003, approximately 3.4% between 2003 and 2004, and approximately 2.8% between 2004 and 2005. These are higher percentages than the 0.5% reflected on the device's label. Another physician presented data from another study at the same meeting, which showed a squeaking rate of 7% for patients who received hip implants from 2003-2005. (Am. Compl. ¶ 34.) Plaintiffs also cite to studies conducted in 2008, indicating a rate of squeaking as high as 20.9%. (Am. Compl. ¶ 35.)

1. Failure to Warn

Plaintiffs' failure to warn claims do not survive. First, plaintiffs have failed to plausibly allege a connection between study results that post-date Mrs. Gelber's July 2004 implant and a duty to warn in July 2004. Plaintiffs fail to explain how defendants could have acted on the findings from these medical studies, when the results of these studies were not presented until 2006, approximately two years after she received her implant. Second, plaintiffs have not identified any federal regulation that required defendants to submit a supplemental premarket approval application based on the clinical findings described by plaintiffs. See Medtronic Leads, 623 F.3d at 1205 (concluding that plaintiffs' failure to warn claims were preempted under section 360k(a)); McMullen v. Medtronic, Inc., 421 F.3d at 489 (stating that "[w]here a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted.") Even assuming, arguendo, that plaintiffs should have submitted a supplemental premarket approval application in 2006 when they received information from these clinical investigations, plaintiffs fail to allege how a failure to update the label warnings any time after 2006 caused Mrs. Gelber's injury. Thus, they have not plausibly alleged a parallel claim. These claims are preempted and therefore dismissed.

2. Failure to Report

Plaintiffs also allege that defendants failed to report the foregoing clinical investigations and findings to the FDA. (Am. Compl. ¶ 37.)

These claims are preempted under Buckman. The Supreme Court explained in Buckman that section 337(a) prohibits a private party from enforcing the MDA. See Buckman, 531 U.S. at 349 n.4 (providing that noncompliance with a MDA provision does not in and of

itself provide a cause of action for a private litigant); 21 U.S.C. § 337(a). The claim also fails to state a claim for relief. There are no facts supporting plaintiffs' allegation, made "upon information and belief," that defendants failed to comply with FDA regulations requiring ongoing reporting of clinical investigations and studies. (Am. Compl. ¶ 37.) Simply setting forth the results of clinical studies revealing rates of side effects different than the rate reported on a FDA approved label does not plausibly allege that defendants failed to comply with FDA reporting requirements where, as here, the studies post-date the FDA approval process and there is no claim that defendants had foreknowledge of the study results. Plaintiffs' claims alleging failure to report are therefore dismissed because they are preempted under Buckman and they fail to state a claim for relief.

C. Plaintiffs' Claims Alleging Failure to Identify and Correct Device Problems Are Dismissed

Plaintiffs also allege that defendants violated numerous CGMP requirements set forth in 21 C.F.R., Part 820 by "fail[ing] to timely identify the causes of the device failure; fail[ing] to evaluate the causes of breakage, stresses in parts and loss of function requiring revision surgery; and fail[ing] to implement effective corrective or preventive actions in order to prevent these problems . . . ." (Am. Compl. ¶ 78.)

These claims do not survive. The FDA approved label acknowledges a 0.5% incidence of squeaking associated with the Trident System and approved the device despite this finding. (Am. Compl. ¶ 29.) Plaintiffs have not set forth facts to plausibly allege that defendants were aware of any associated grinding related to the squeaking or a higher than believed incidence rate before July 2004, such that they could have remedied the problem before Mrs. Gelber received her implant. The FDA Warning Letter, as described by plaintiffs, states that

complaints regarding squeaking and device failure did not surface until January 2005, and research studies indicating a higher than predicted incidence of squeaking were not reported until a medical conference in 2006. (Am. Comp. ¶¶ 29, 32-35, 40.)

Moreover, imposing liability on defendants for "fail[ing] to implement effective corrective or preventive actions" or "fail[ing] to timely identify the causes of the device failure" would impose additional state law requirements on defendants. The regulations that appear to be at the heart of these allegations provide as follows:

> § 820.100 Corrective and preventive action.
>
> (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:
>
> (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
>
> (2) Investigating the cause of nonconformities relating to product, processes, and the quality system;
>
> (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
>
> (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
>
> (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
>
> (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

> (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.
>
> (b) All activities required under this section, and their results, shall be documented.

21 C.F.R. § 820.100.

These regulations include a provision that addresses a manufacturer's obligation to "establish and maintain procedures for implementing corrective and preventive action." 21 C.F.R. § 820.100(a). They also require manufacturers to "establish and maintain procedures" for "[i]nvestigating the cause of nonconformities relating to product, processes, and the quality system" and "[i]dentifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems." 21 C.F.R. § 820.100(a)(2)-(3).

These federal regulations do not impose on defendants any obligation to "*timely* identify the causes of the device failure," or "to implement *effective* corrective or preventive actions in order to prevent these problems . . . ." (Am. Compl. ¶ 78)(emphasis added.) Cf. Howard, 382 Fed.Appx. at 441 (interpreting a different CGMP requirement, set forth in 21 C.F.R. § 820.70(h), which provides, in part, "the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed . . ." to mean that actual removal of the material is required.) The inherent nature of Class III medical devices approved under the premarket approval process is that, at least without great oversight, they pose a high risk to the public. 21 U.S.C. § 360c(a)(1)(C). Undoubtedly, some problems associated with Class III medical devices are never resolved, but the failure to resolve a problem does not necessarily mean that the manufacturer violated federal regulations. See Riegel, 552 U.S. at 318 (stating that the FDA may approve a Class III medical device under the premarket approval process for "devices that

present great risks if they nonetheless offer great benefits in light of available alternatives" and explaining that the FDA "approved, for example, under its Humanitarian Device Exemption procedures, a ventricular assist device for children with failing hearts, even though the survival rate of children using the device was less than 50 percent.") If this Court were to instruct a jury that it may find the defendants negligent because they did not timely identify and fix the source of squeaking, this would impose on defendants an additional burden that is not imposed on them by the federal regulations. This lays at the heart of preemption under the MDA. Riegel, 552 U.S. at 321-22 (citing 21 U.S.C. § 360k(a)) (providing that state law claims are preempted where the court "determine[s] [that] the [plaintiffs'] common-law claims are based upon New York requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety or effectiveness."). Thus, these claims are preempted and therefore are dismissed.

D. Plaintiffs' Claims Alleging a Failure to Control Nonconforming Product Are Dismissed

In attempting to plead a negligence claim that is not preempted under section 360k(a), plaintiffs allege that defendants took "no effective action . . . to control nonconforming product in distribution" even though Stryker's "own analyses showed an increase in complaints." (Am. Compl. ¶¶ 44, 78.) They allege that "[d]efendants' failure to meet [these] federal requirements . . . , directly and proximately caused [p]laintiff's implant to be defective." (Am. Compl. ¶ 70.)

The FDA regulation addressing nonconforming medical devices provides:

> 820.90 Nonconforming product.
>
> (a) Control of nonconforming product. Each manufacturer shall establish and maintain procedures to control product that does not conform to

> specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.
>
> (b) Nonconformity review and disposition.
>
> > (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.
> >
> > (2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

21 C.F.R. § 820.90.

Construing plaintiffs' allegations liberally, they allege that the product was nonconforming because there was excessive manufacturing residue on the Trident System and because the incidence of squeaking was higher than anticipated. (Am. Compl. ¶¶ 43-44, 46.) Plaintiffs have failed to set forth facts to plausibly allege that defendants violated federal regulations relating to nonconforming medical devices. With respect to the former allegation, plaintiffs have not set forth any facts indicating that defendants knew or should have known before July 2004, the date Mrs. Gelber received her hip implant, that the Trident System Mrs. Gelber received was defectively manufactured because it had excessive manufacturing residue. Without plausibly alleging that defendants knew or should have known that the product did not conform to manufacturing specifications at the time Mrs. Gelber received her hip implant,

plaintiffs have failed to adequately allege that defendants violated these nonconforming device regulations in a manner that they can link to Mrs. Gelber's injury. Cf. Bausch, 630 F.3d at 559 (concluding that plaintiffs' claims alleging that defendants failed to comply with nonconforming product regulation were not preempted by federal law where plaintiffs "alleged facts indicating that defendants knew, or at least should have known, before plaintiff's original surgery that the Trident implanted in her was defective.")

With respect to the latter allegation, plaintiffs allege "upon information and belief" that "prior to the implantation of [p]laintiff's . . . Trident System, [d]efendants were aware of complaints of audible noise emanating from its . . . Trident devices . . . ." (Am. Compl. ¶ 28.) Plaintiffs further allege that despite "[d]efendants own analyses show[ing] an increase in complaints, no effective action was taken by [d]efendants to control nonconforming product in distribution." (Am. Compl. ¶ 44.)

Knowledge by defendants that the Trident System implanted in Mrs. Gelber posed a *risk* of squeaking does not mean that defendants failed to follow federal regulations addressing nonconforming devices. The FDA-approved label on the Trident System acknowledged squeaking as a recognized side effect associated with the use of the Trident System. (Am. Compl. ¶ 29.) Plaintiffs also refer to "defendants own analyses" of the complaints, but they fail to explain what these analyses were, when they were conducted, or the findings of these analyses.

Imposing a requirement on defendants to control nonconforming product they neither knew nor should have known was nonconforming would impose an additional state law burden on defendants. Plaintiffs' claims alleging a failure to control nonconforming product claim are therefore preempted and thus dismissed.

E. Plaintiffs' Claims Alleging a Failure to Develop Practices and Procedures Are Dismissed

Plaintiffs also allege that defendants "failed to develop practices and procedures" to assure compliance with multiple federal regulations including 21 C.F.R. § 803, which requires device manufacturers to report deaths and serious injuries that a device may have caused or contributed to causing; section 806, which requires device manufacturers to report device corrections and removals as well as to maintain records of all corrections and removals; section 820, which requires device manufacturers to comply with the CGMP requirements; as well as 21 U.S.C. § 360, which addresses the registration of producers of drugs or devices. (Am. Compl. ¶¶ 67-68.) To the extent these vague and conclusory allegations are not impliedly preempted, because a private individual cannot bring an action for violating FDA regulations, plaintiffs have failed to set forth facts to plausibly allege how defendants violated these provisions or how Mrs. Gelber's injury is linked to any such violation. See Buckman, 531 U.S. at 353 (providing that noncompliance with a MDA provision does not in and of itself provide a cause of action for a private litigant). These claims are therefore dismissed.

F. Plaintiffs' Breach of Express Warranty Claims Survive

Plaintiffs also assert claims alleging breach of express and implied warranties. (Am. Compl. ¶¶ 59-61, 90-100.)

1. Breach of Express Warranty

To state a claim for breach of express warranty, the plaintiff must show that there was an "affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase, and that the warranty was relied upon." Schimmenti v. Ply Gem

Indus., Inc., 549 N.Y.S.2d 152, 154 (2d Dep't 1989) (quoting Friedman v. Medtronic, Inc., 345 N.Y.S.2d 637, 643 (2d Dep't 1973).

Construing plaintiffs' allegations liberally, plaintiffs allege that they relied to their detriment on defendants' express representations set forth in Trident System packaging material that (1) "[t]he ceramic in [p]laintiff's Trident was extremely hard and provided excellent lubrication between the ball and socket, (2) "[t]he [p]laintiff's Trident had improved wear characteristics that would extend the life of the implant in [p]laintiff," and (3) "that [p]laintiff's Trident offered a stronger, easier-to-use ceramic liner." (Am. Compl. ¶¶ 59-61, 99.)

These claims are not preempted and state a claim upon which relief can be granted. Defendants do not argue that these representations arose by virtue of defendants' participation in the premarket approval process, nor, based on the content of these representations, does it appear that they did. Rather, it appears they arose from the warrantor. Cf. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 525 (1992) (explaining, in the context of discussing preemption under the Federal Cigarette Labeling and Advertising Act, that "requirements" arising from express warranties are imposed by the warrantor, and not state law). Thus, imposing liability on defendants for violating these express warranties would not impose any additional state law obligations on defendants. See Mitchell v. Collagen Corp., 126 F.3d 902, 915 (7th Cir. 1997) ("A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the [premarket approval process], and therefore we cannot say that such a cause of action is preempted."); Horowitz, 613 F. Supp. 2d at 285 (noting that a breach of express warranty "based on non-FDA-approved representations" would survive preemption.) These claims therefore survive the motion to dismiss.

However, to the extent plaintiffs' allege that defendants represented that (4) the Trident System was safe and effective for its intended purpose and (5) the defendants complied with the manufacturing specifications set forth in the premarket approval application submitted to the FDA, these claims fail to state a claim for relief and are therefore dismissed. (Am. Compl. ¶ 96.) Plaintiffs have failed to adequately identify the actionable conduct on the part of the defendants. For example, the Amended Complaint does not allege where these alleged representations appeared or to whom they were made. All Class III medical devices approved under the premarket approval process represent, at least to the FDA, that they comply with the FDA-approved premarket approval specifications and are safe and effective for its intended purpose. Plaintiffs have failed to set forth facts indicating that any such express representation was made to Mrs. Gelber. See Horowitz, 613 F. Supp. 2d at 286 (citing Lake v. Kardjian, 874 N.Y.S.2d 751, 754 (N.Y.Sup.Ct. 2008) (noting that the express warranty claims failed to give defendants sufficient notice of the claim where, among other reasons, plaintiffs failed to describe where the representations were made). Although plaintiffs have attached patient labeling information and advertising material to their opposition memorandum, (Rosenrauch Dec. Ex. B), they may not amend their pleadings in their brief, or by material attached to their brief. Wright v. Ernst & Young LLP, 152 F.3d 169, 178 (2d Cir. 1998) (noting that a party may not amend pleadings through statement in its motion brief). Nor has this Court considered material outside the pleadings in deciding this motion to dismiss.

Because these express warranty claims are not dismissed as time-barred, as explained below, defendants' motion to dismiss plaintiffs' breach of express warranty claims relating to representations (1) through (3) is denied.

2. Breach of Implied Warranty

Plaintiffs allege that defendants breached their implied warranty of merchantability by selling plaintiffs an adulterated device because the Trident System was unfit for its ordinary purpose. (Am. Compl. ¶¶ 92-93.) Plaintiffs' implied warranty claims are not preempted to the extent they allege a defective manufacturing claim, but as explained below, these claims are barred by the statute of limitations.

STATUTE OF LIMITATIONS AS APPLIED TO THE EXPRESS AND IMPLIED WARRANTY CLAIMS

The parties proceed from the assumption that New York law governs this diversity action, so this Court will apply New York law. See Krumme v. WestPoint Stevens Inc., 238 F.3d 133, 138 (2d Cir. 2000) (noting that the implied consent of parties to the application of New York law is sufficient to establish choice of law). Under New York law, the usual limitations period for breach-of-warranty claims is four years from the date when tender of delivery is made. N.Y. U.C.C. § 2-725(2); Heller v. U.S. Suzuki Motor Corp., 64 N.Y.2d 407, 410 (1985). But "where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered." N.Y. U.C.C. § 2-725(2); Mittasch v. Seal Lock Burial Vault, Inc., 344 N.Y.S.2d 101, 102 (2d Dep't 1973). "[T]he term 'explicit' has been explained as plain language which is distinctly stated, clear and unequivocal to the point that there is no doubt as to its meaning." Port Auth. of N.Y. & N.J. v. Allied Corp., 914 F. Supp. 960, 962 (S.D.N.Y. 1995) (citation omitted). "A warranty of future performance is one that guarantees that the product will work for a specified period of time." St. Patrick's Home for Aged and Infirm v. Laticrete Intern., Inc., 696 N.Y.S.2d 117, 123 (1st Dep't 1999). However,

"[w]arranties to repair or replace the product in the event that it fails to perform, without any promise of performance, do not constitute warranties of future performance." Id.

1. Plaintiffs' Breach of Implied Warranty Claim Is Time-Barred

Defendants delivered the Trident System to the plaintiffs no later than July 2004, the month in which Mrs. Gelber received the implant. Because the future performance exception does not apply to plaintiffs' implied warranty claims, plaintiffs' claim accrued and the four-year statute of limitations began to run in July 2004 at the latest. See Orlando v. Novurania of America, Inc., 162 F. Supp. 2d 220, 224 (S.D.N.Y. 2001) ("The [future performance] exception speaks to express warranties not implied warranties."); Allied Corp., 914 F. Supp. at 963 (stating that "[l]ogically, implied warranties cannot explicitly extend to future performance.") The statute of limitations therefore expired in July 2008, well before plaintiffs commenced this action in 2009. Thus, plaintiffs' breach of implied warranty claim is dismissed as time-barred.

2. Plaintiffs' Breach of Express Warranty Claims Are Not Time-Barred

Plaintiffs argue that there are questions of fact with respect to whether the express warranties made by defendants extended to future performance of the Trident System. (Pls. Mem. 15.) Plaintiffs have included an affidavit with Stryker marketing and labeling information with their opposition memorandum. (Rosenrauch Dec. Ex. B.)

This Court is unable to determine from the face of the Amended Complaint whether the express warranties alleged by plaintiffs explicitly refer to future performance or not. Because this Court may only grant defendants' motion to dismiss the express warranty claims if it is clear from the face of the complaint that they are time-barred, and it is not clear under the facts alleged, this Court will allow the claims to stand

for now and will permit defendants to revisit the issue at the summary judgment stage. See Wiltshire v. A. J. Robins Co., Inc., 453 N.Y.S.2d 72, 74 (3rd Dep't 1982) (citing Peterson v. Spartan Ind., 33 N.Y.2d 463, 466 (1982) (stating that the motion to dismiss was granted prematurely "because the record [was] insufficient to permit a determination as to whether the warranties alleged explicitly referred to future performance" and noting that the "information . . . may well be peculiarly within the control of defendant . . . and plaintiffs should be afforded the opportunity to elicit such facts through disclosure"); Weiss v. Herman, 597 N.Y.S.2d 52, 53 (1st Dep't 1993) (explaining that an express warranty for future performance "can stem from the literature disseminated by the manufacturer to the medical profession.") (citation omitted). Defendants' motion to dismiss plaintiffs' express warranty claims as time-barred is therefore denied.

CONCLUSION

For the reasons stated above, defendants' motion to dismiss (Docket #21) is granted in part and denied in part. Plaintiffs' defective manufacturing claims sounding in negligence and strict products liability survive the motion to dismiss. Certain of plaintiffs' breach of express warranty claims also survive, as set forth above. Because the loss of consortium claim is derivative of Mrs. Gelber's claims, this claim survives only to the extent the underlying claims survive. The remaining claims are dismissed.

SO ORDERED.

P. Kevin Castel
United States District Judge

Dated: New York, New York
April 18, 2011